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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

WILLIAMSON, M

ART UNIT

PAPER NUMBER

1616

DATE MAILED:

12/06/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/435,576

Applicant(s)

Cohen et al

Examiner

W/Hanson

Group Art Unit

16/6

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on _____.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-15 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-15 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

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DETAILED ACTION

Pending Claims

The pending claims in the instant application are 1 -75. The independent claims are 1, 48, 51, 58, 62, 70-72 and 74.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-75 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a controlled release oral solid dosage form comprising a core of an alkyl ester of a hydroxy substituted naphthalene compound, a pharmaceutically acceptable , water swellable polymer and an osmotic agent and an outer coating layer which completely covers the core comprising a pH sensitive coating agent and a water insoluble polymer used at a weight ratio of about 0.1:1 to 0.75:1 at a combined coating weight of 0.5-5% by weight, does not reasonably provide enablement for a controlled release oral

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solid dosage formulation without the recited limitations regarding a core and an outer coating having the weight ratio and combined coating weight. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The limitation recited above regarding the core and the coating as well as the ratio of pH sensitive polymer to insoluble polymer and the total weight used are critical to the invention because the ratios and weights falling significantly outside these boundaries will not have the required dissolution properties and without the outer coating of the core the composition will not be controlled release.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321[©] may be used to overcome an actual or provisional rejection based on a nonstatutory double

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patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-75 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 5,916,595. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims use open language which allows for the additional components recited. Additionally, the functional language recited in the instant application is met by the patented claimed materials used as well as the structure recited.

5.

Crystal Mall 1 Facsimile Center

A facsimile center has been established in Crystal Mall 1, room 7C10. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is (703) 308-4556. The new location should be used in all instances when faxing any correspondence to Group 1600. Use of the new Crystal Mall 1 center will facilitate rapid delivery of materials to the Group. The faxing of all papers must conform with the notice published in the Official Gazette, 1096 O.G. 30 (November 15, 1989).

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6. Any inquiry concerning this communication or earlier communication from the examiner should be directed to Michael A. Williamson whose telephone number is (703) 308-1235.



Michael A. Williamson
Patent Examiner
Group 1610

Williamson001204
December 4, 2000